



Australian Government

Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

ANZHSN

AN INITIATIVE OF THE NATIONAL, STATE AND
TERRITORY GOVERNMENTS OF AUSTRALIA
AND THE GOVERNMENT OF NEW ZEALAND

National Horizon Scanning Unit

Horizon scanning prioritising summary

Volume 5, Number 6:

**Guardian™ Continuous Glucose Monitoring
System: Blood glucose monitoring in
diabetic patients.**

May 2004



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The production of this *Horizon scanning prioritising summary* was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

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PRIORITISING SUMMARY

REGISTER ID: 000097

NAME OF TECHNOLOGY: GUARDIAN™ CONTINUOUS GLUCOSE MONITORING SYSTEM

PURPOSE AND TARGET GROUP: BLOOD GLUCOSE MONITORING IN DIABETIC PATIENTS

STAGE OF DEVELOPMENT (IN AUSTRALIA AND/OR NEW ZEALAND):

- | | |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | |
|--|---|
| <input type="checkbox"/> Yes | ARTG number |
| <input checked="" type="checkbox"/> No | <input type="checkbox"/> Not applicable |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States	✓		

IMPACT SUMMARY:

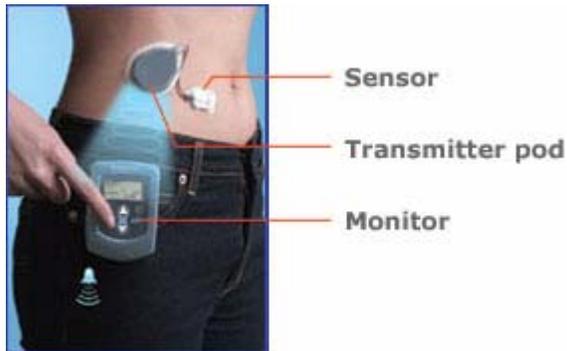
Medtronic Minimed provides The Guardian™ Continuous Glucose Monitoring System for Type 1 or 2 diabetic patients to monitor blood glucose levels. The Guardian™ is the most recent model of the previous Continuous Glucose Monitoring System approved in the United States in March, 2003. The Guardian™ received American Food and Drug Administration pre-market approval in January, 2004. It is not yet available in Australia.

BACKGROUND

The Guardian Continuous Glucose Monitoring System is an external device that can continuously record blood sugar levels using a glucose sensor. The readings can be stored for up to three days in a monitor, which will sound an alarm when the blood glucose levels reach the highest or lowest limit pre-set by the patient or healthcare professional. The recordings can be downloaded from the monitor to a computer.

The Guardian™ Continuous Glucose Monitoring System requires a prescription from a physician and calibration needs to occur with a finger prick test, thus not eliminating finger prick testing. The monitor included in the Guardian™ Continuous Glucose Monitoring System can store up to 21 days of sensor glucose readings. These readings can be downloaded to a personal computer

for review. The information gained from the monitor can help to detect trends in glucose levels, which may help to improve the management of diabetes (Minimed 2004).



Source: http://www.minimed.com/patientfam/images/pf_ipt_guardian_howworks.jpg

The Guardian™ Continuous Glucose Monitoring System has three components that form the basis of the monitor. The sensor, which is inserted just under the skin records glucose levels using interstitial fluid from the layer of fat between skin and muscle. The sensor is designed to be worn for up to three days. To calibrate the sensor, the user must enter glucose readings from a traditional, fingerstick monitor at least twice each day. The system's transmitter receives blood glucose readings from the sensor. It then relays this information to a monitor using radio waves. The transmitter can be worn under clothing.

The monitor can be worn on a belt, or placed in a pocket or a purse and needs to be within 6 feet of the transmitter to be able to receive signals. The monitor is about the size of a pager. The monitor records glucose readings received from the sensor (via the transmitter). It is designed to sound an alarm if the patient's glucose readings fall out of range. The user or healthcare provider can pre-set the monitor with the desired glucose ranges prior to use. For example, a low target of 70 mg/dL and a high target of 200 mg/dL are set, the monitor is designed to alert the user when it detects a reading outside of these targets. The previous Medtronic Minimed continuous glucose monitors do not provide real-time alarm feature and do not permit the user to set targets and is larger in size.

The downloading system, which includes software and hardware, allows glucose values that have been stored in the monitor to be downloaded to a PC. The software can graph the values so that the user and health care provider can view trends in blood glucose control.

CLINICAL NEED AND BURDEN OF DISEASE

Diabetics need to check their blood glucose levels at least three times a day using a standard finger prick test. This method is invasive, painful and sometimes quite difficult to perform.

It is estimated that approximately one million people suffer from the three types of diabetes (Type-1, Type-2 and gestational diabetes) in Australia. In the year 2000, diabetes was the underlying cause of death of over 3,000 (2.3%) of Australians.

However, diabetes is twice as likely to be an associated cause of death rather than the underlying cause, with over 10,000 recorded with diabetes as an underlying or associated cause of death. It is difficult to estimate the proportion of morbidity associated with diabetes, however in 1999-2000 12 per cent of patients aged over 25 years with diabetes suffered a heart attack and nine per cent a

stroke. In addition, 15 per cent of diabetics had retinopathy, 6 per cent kidney disease, approximately 10 per cent had neuropathy, 19 per cent were at risk of foot ulcers and 2 per cent had amputated limbs. In 1998 almost 64,000 Australians had a disability caused by diabetes (AIHW, 2002 chapter 6).

In 2000-01, it was estimated that 2.9 million consultations occur each year with GPs to manage diabetes. (AIHW 2002, Chapter 5)

DIFFUSION

Given that the Guardian™ does not rule out the use of finger-stick testing and the cost is quite considerable, uptake of the device may be minimal. Currently it is not yet available in Australia.

COMPARATORS

Patients who are insulin dependent are required to monitor their blood glucose levels to ensure that appropriate levels of insulin are circulating. Finger-prick testing is painful, inconvenient and messy, therefore a non-invasive method for measurement of blood glucose levels is being actively sought. In addition, stress and anxiety may be exacerbated for children suffering from diabetes and their parents. Daily self-monitoring and missing insulin injections remain serious problems for many diabetic patients (Altobelli 2000)

The company notes that The Guardian™ System is not intended to replace fingerstick testing. At a minimum, the Guardian system must be calibrated using a home glucose meter at least every 12 hours. Additional calibrations will result in better system performance. Low or high glucose alerts from the Guardian system should be verified using a home glucose meter before taking any action (Minimed 2004).

COST IMPACT

Newly diagnosed diabetic patients are issued with a National Diabetic Supply Scheme (NDSS) card. The NDSS is a Commonwealth Government registration scheme, which provides a subsidy for blood glucose testing strips and free insulin syringes and free needles for insulin delivery pens. The NDSS does not provide a subsidy for blood glucose meters, lancets or lancet devices. By quoting their unique NDSS number, patients may order testing strips from their local diabetic association. Testing strips and lancets currently cost approximately \$13 (packet 100) and \$16 (packet of 200), respectively and would cost a total of approximately 64 cents per day if patients tested three times daily (personal communication, Diabetes South Australia).

A continuous glucose monitoring system from Medtronic Australia currently costs \$5,800.00 (Medtronic Australia, personal communication). The use of continuous monitoring systems does not attract any government subsidy. It is expected that the Guardian™ will cost a similar amount.

EFFECTIVENESS AND SAFETY ISSUES

The most recent study published reported on the accuracy and effectiveness of the Guardian™ Continuous Monitoring System to alert users to hypo and hyperglycaemia in a multicentre, randomised, controlled study (level II evidence) in 71 patients with type I diabetes (Bode et al 2004). The study participants were aged 44± 11 years and duration of diabetes was 23.6±10.6years. Blood glucose readings were taken for two time periods. Subjects were randomized into either a Guardian™ group or a control group using fingerstick testing alone.

Reported results show that the Guardian™ readings varied 21.3% from the fingerstick readings and that on average read 12.8 mg/dl below fingerstick readings. Subjects in the Guardian™

group experienced a median decrease of 27.8 minutes in the duration of hypoglycemic episodes compared to a decrease of 4.5 minutes in the control group (fingerstick testing) between the two periods of readings ($p=.03$). The hypoglycemia alert in the Guardian™ distinguished glucose values ≤ 70 mg/dL with 67% sensitivity, 90% specificity, and produced 47% false alerts. The hyperglycaemia alert in the Guardian™ detected sensor values ≥ 250 mg/dL with 63% sensitivity, 97% specificity, and produced 19% false alerts.

It was not possible to source other studies with the Guardian™ Continuous Monitoring System although there are numerous studies reporting on effectiveness of the previous Continuous Monitoring System in different groups.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

CONCLUSION:

There is currently limited evidence available on the safety and effectiveness of the Guardian™ Continuous Monitoring System. However, the prevalence of diabetes and diabetes-associated morbidity in Australia is high and there is the potential for a rapid uptake of this technology.

HEALTHPACT ACTION:

Therefore it is recommended that this technology be monitored.

SOURCES OF FURTHER INFORMATION:

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SEARCH CRITERIA TO BE USED:

Blood Glucose/ analysis
Blood Glucose Self-Monitoring/instrumentation/ methods
Blood Glucose Self-Monitoring/methods
Diabetes Mellitus, Type I/ blood